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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,317	01/27/2004	M. Peter Marinkovich	33828/US/RFT/RMK	1212

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EXAMINER	
HALVORSON, MARK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,317	MARINKOVICH, M. PETER	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *8-11 and 13-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/3/2006;4/25/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence search*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-13 in the reply filed on June 19, 2006 is acknowledged. Applicant's election of SEQ ID NO:21 is acknowledged. Claims 8-11, 13-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 1-7 and 12 are under prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-7 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3 are drawn to an antibody that specifically binds a migration facilitating protein (MFP) comprising a laminin 5 alpha 3 G4 and/or 5 domain or subdomain.

The specification defines " MFPs" as proteins that are capable of supporting migration of nearby tissue or tissue located at distal points in the body by neoplastic

epithelial cells. The specifications discloses 3 defined MFPs (MFP5, 6 and 8) and a number of undefined MFPs (see Figs. 1A-D). MFPs can from 8 to 315 amino acids (see paragraph 81-83).

The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

The Federal Circuit has recently clarified that a molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

Thus, the instant specification may provide an adequate written description of polypeptide antagonists, per Lilly by structurally describing a representative number of MFPs that function as claimed or by describing structural features common to the members of the genus, which features constitute a substantial portion of the genus. Alternatively, per Enzo, the specification can show that the claimed invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

In this case, the specification does not describe the genus of MFPs in a manner that satisfies either the Lilly or Enzo standards. There are insufficient structural features common to all members of the genus of MFPs. The claims are drawn to antibodies that bind "MFP". Thus, the scope of the claims includes a genus of "MFP" polypeptides and the genus is highly variant inclusive to numerous structural variants because a significant number of structural differences between genus members is permitted. The specification defines MFPs as proteins that are capable of supporting migration of nearby tissue or tissue located at distal points in the body by neoplastic epithelial cells. MFPs can from 8 to 315 amino acids (see paragraph 081-083). The specification states that MFPs encoding other subdomains within the laminin 5 alpha 3 G4 and/or 5 domains can also be generated and used in the methods of the present invention (paragraph 004). Thus, the genus of MFPs include a vast number of peptides that vary in length from 8 to 315 amino acids.

Furthermore, the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.").< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). MPEP 2111.02. Thus, the claims encompass MFPs of laminin alpha 3 G4 and/or 5 domain or subdomains and other structural components which would be a myriad of peptides and peptide conjugates. The specifications only discloses 3 defined MFPs (MFP5, 6 and 8) of the alpha chain of laminin 5 and a number of undefined MFPs (see Figs. 1A-D).

The genus of MFPs encompasses a myriad of peptides and peptide conjugates. There is no structural similarity between the genus of MPPs as defined in the specification. The genus includes peptides which have no sequence similarity to other peptides within the genus. The limited number of MFP peptides defined in the specification does not sufficiently describe the genus of polypeptide antagonists do not meet the standard set forth in Lilly.

The instant specification may also provide an adequate written description of the genus of polypeptide antagonists if the specification can show that the claimed invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. The specification

discloses a limited number of MFP peptides and discloses no information on MFP peptides that would function as claimed, that is to be bound by antibody and treat squamous cell carcinoma. The is no information in the specification concerning which sequence or sequences of the myriad of peptides would function as claimed. Thus, the specification does not describe sufficient structural characteristics that correlate with the ability of the genus of MFP peptides to function as contemplated by the specification and for the reasons set forth above do not meet the standards set forth by Enzo.

Thus, the specification does not provide an adequate written description of the genus of genus of MFP peptides and peptide conjugates of claims 1-7 and 12 that is required to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter et al US Patent No:6, 120, 991, issued Sept 19, 2000.

The claims are drawn to a composition for treating squamous cell carcinoma comprising an antibody that specifically binds a migration facilitating protein comprising a laminin 5 alpha 3 G4 and/or 5 domain and a pharmaceutically acceptable carrier wherein the antibody is a polyclonal antibody, wherein the antibody is a monoclonal

antibody, wherein the migration facilitating protein has a sequence comprising the amino acid of SEQ ID NO:21.

Carter et al disclose monoclonal and polyclonal antibodies to epilgrin (see Example 2) and disclose an $\alpha 3$ chain of epilgrin (SEQ ID NO:24) that comprises the amino acid sequence of SEQ ID NO:21 of the present application (see Search Results). The transitional term "comprising", which is synonymous with "including," "containing," or"characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.").< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). MPEP 2111.02. Antibodies generated to the protein, epilgrin that comprises the amino acid sequence of SEQ ID NO:21 would bind to the migration facilitating protein comprising the amino acid sequence of SEQ ID NO:21.

Summary

3. No claims allowed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JEFFREY SIEW
SUPERVISORY PATENT EXAMINER